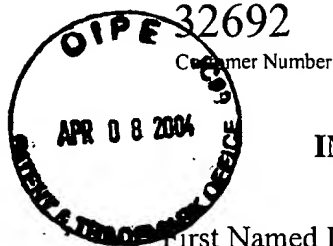


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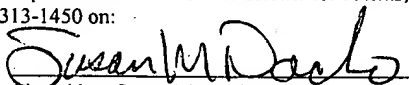


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: JAPUNTICH, DANIEL A.
Application No.: 09/837800 Group Art Unit: 3743
Filed: April 18, 2001 Examiner: Aaron J. Lewis
Title: FILTERING FACE MASK THAT HAS A NEW EXHALATION VALVE

BRIEF ON APPEAL

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P.O. Box 1450
Alexandria, VA 22313-1450

<u>CERTIFICATE OF MAILING</u>	
I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:	
April 5, 2004 Date	 Signed by: Susan M. Dacko

Dear Sir:

This is an appeal from the Office Action mailed on November 4, 2003. This Brief is being filed in triplicate. The fee required under 37 CFR § 1.17(c) for the appeal should be charged to Deposit Account No. 13-3723.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

The following applications are currently under appeal: U.S. Serial Nos. 08/240,877, 09/678,579, 09/680,465, 09/678,580, and 09/837,714.

STATUS OF CLAIMS

Claims 33-37, 50-53, and 55-88 are pending in this case and are the subject of this appeal. A copy of these claims is set forth in the Appendix to this Brief on Appeal.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF THE INVENTION

Persons who work in contaminated environments commonly wear filtering face masks over their nose and mouth to protect themselves from inhaling airborne pollutants. Many known filtering face masks have employed a cup-shaped mask body that includes a filter layer and that is adapted to fit over a wearer's nose and mouth. Exhalation valves have been used on these masks to rapidly purge exhaled air from the mask interior. The rapid removal of exhaled air makes the mask more comfortable to wear.

Because exhalation valves are powered by the wearer's lungs, valves that open easier during each exhalation improve wearer comfort because less work is needed to operate the valve. Valves that open easier may also be beneficial in that they can more rapidly purge warm, moist, exhaled air from the mask interior. Hot moist air can be very uncomfortable, particularly when working in a warm environment. In the working examples of the present invention, applicants have demonstrated an ability to remove so much air (>100%) from the mask interior, during a simulated exhalation, that an influx of cool ambient air occurred (see Table 2, particularly Examples 11-13). For filtering face masks that have porous mask bodies, this is quite an achievement because it demonstrates, for the first time, that a filtering face mask can operate as a cool-air aspirator — drawing cool, low humidity, air into the mask interior through the filter media during an exhalation to substantially improve wearer comfort. No prior art exhalation valve on a filtering face mask had yet demonstrated such a feat during an exhalation, particularly on a valve that is capable of having its flap remained closed under any mask orientation.

The most common type of exhalation valve that has been used on filtering face masks is a "button-style" valve. These valves typically have a circular flexible flap that is mounted to a valve seat through a central stake or button. The whole circumference of the flap is generally free to be lifted from the seal surface during an exhalation. An example of a button-style valve is shown in Figure 3 (cross-sectional side view) of UK patent application GB 2,072,516A to Simpson:

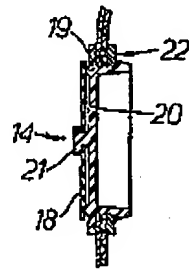


FIG. 3.

[Simpson Button-Style Valve]

Another example of a button-style valve is shown in U.S. Patent 4,873,972 to Magidson et al., assigned to Moldex/Metric Products Inc. and issued on October 17, 1989.

In addition to button-style valves, other valve structures have been used to purge exhaled air from the mask interior. For example, U.S. Patent 4,934,362 to Braun describes a valve, which when viewed from the side, has a parabolic valve seat. Like the button-style valves, the Braun valve has its flap mounted centrally to the valve seat:

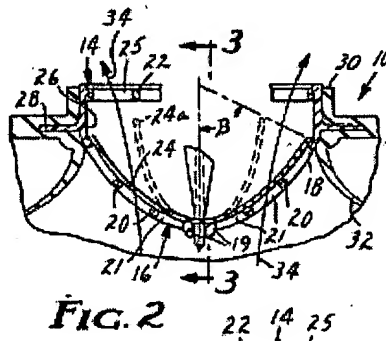


FIG. 2

This central mounting, however, can interfere with the flow of exhaled air through the valve and can cause exhaled air to be diverted into multiple flow streams, which requires two shorter free ends for the flap (as opposed to a flap with one free portion) and which accordingly increases the moment arm that is needed to lift the flap from the seal surface. For these reasons, centrally-mounted valves may not perform as well as the valve invented by the appellants.¹

¹ Examples 4-6 in applicants' specification show the performance of the Braun valve compared to applicants' invention.

As an alternative to a centrally-mounted valves, a "flapper-style" or "cantilevered" valve also has been disclosed as being suitable for use on filtering face masks. Figure 2 of the Simpson patent shows such a valve:

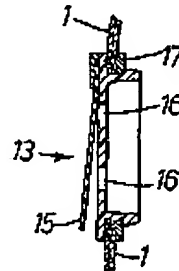
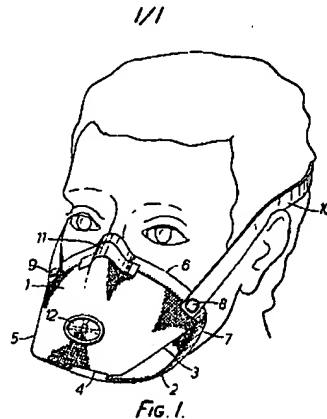


FIG. 2.

[Simpson's Flapper Valve]

This flapper-style valve includes a "flexible circular flap member 15 of, for example, plastics material, which is arranged to cover and close valve opening 16 during an inhalation and to flex away from those openings during exhalation." To enable the flap member to flex, "a part of its peripheral portion, a segment of the flap member, is fixed in position, the remaining part of the flap member being left free." See Simpson at page 2, lines 37-46.

Although Simpson's flapper-style valve can provide a greater moment arm (than a centrally-mounted flap) for lifting the flap 15 from the seal surface to encourage quick displacement of exhaled air from the mask interior, the valve does suffer from a number of deficiencies, amongst them, the inability to keep the flap closed under any orientation of the valve. To keep its valve closed under neutral conditions — that is, when a wearer is neither inhaling nor exhaling — Simpson mounts the valve 12 on the top portion 1 of its duck-billed mask:



[Simpson Mask]

Simpson does not describe how to construct a flapper-style valve where the flap is pressed against a seal surface when a wearer is neither inhaling or exhaling. Simpson's valve therefore relies on gravity for this purpose. This reliance on gravity, however, places limits on the locations where Simpson's valve can be placed on a cup-shaped mask without risking contaminant influx. And when the valve is not disposed directly in (or normal to) the path of the exhaled flow stream, the flap cannot take full advantage of the momentum of the exhale flow stream during an exhalation to encourage more rapid and complete opening of the valve. Without this ability, the displacement of exhaled air cannot be maximized, and aspiration effects are less likely to occur. In addition, because the Simpson valve does not have a pre-load on it, there is a great risk that the valve could remain open under certain conditions. Saliva and moisture commonly build up on an exhalation valve during use. The presence of these substances on the flap can cause the flap to stick to another surface such as a valve cover, when the flap opens in response to a force from an exhalation, or in Simpson's case from mere gravity. Without a preload, the possibility is greater that the flap will stick open. If the valve stays open, then contaminants can be directly drawn into the wearer's respiratory system during the next inhalation. Because the valve flap is not biased, Simpson recognizes that its valve may leak and accordingly suggests the use of an "antechamber" to prevent inhalation of "harmful atmosphere". See Simpson at p. 1 lines 58-64. The antechamber solution that Simpson proposes is entirely different from the structural solution proposed and claimed by the applicants of the subject invention.

Applicants' invention pertains to a filtering face mask 10 that comprises a mask body 12 that is adapted to fit over the nose and mouth of a wearer. The filtering face mask 10 also has an exhalation valve 14 that is attached to the mask body 10 directly in the path of the exhale flow stream. The exhalation valve comprises a valve seat 26 and a single flexible flap 24.

In applicants' invention, the flap 24 is supported on a valve seat 26 to provide a mask that exhibits better in performance over known exhalation valves:

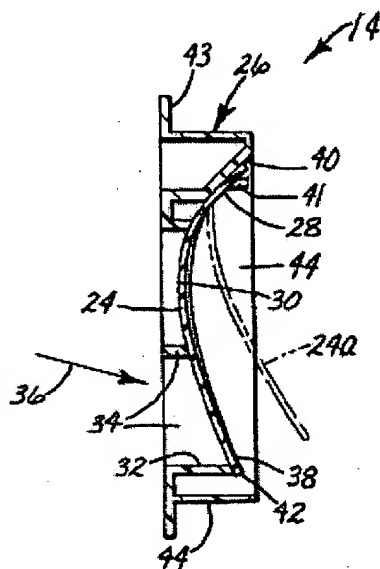


Fig. 3

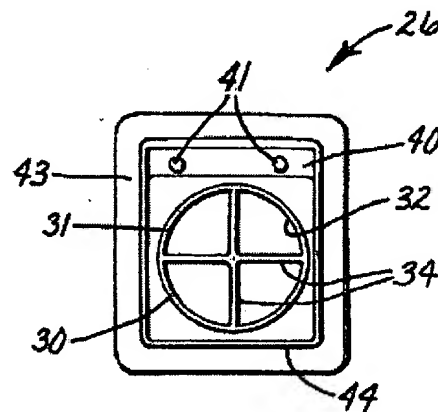


Fig. 4

[Applicants' Valve]

In applicants' flapper valve or cantilevered, the flexible flap 24 is mounted to the valve seat 26 such that the one free portion 38 of the flap 24 exhibits a curvature over the orifice area 32 when viewed from the side in the closed position and is pressed towards the seal surface 31 in an abutting relationship with it, under any orientation of the valve, when a fluid is not passing through the orifice.

Applicants' invention exerts a bias on the flap to prevent the unwanted influx of contaminants. Despite the bias, the flap's one free portion 38, however, can be readily lifted from the seal surface during an exhalation (as a bent cantilever) to allow large quantities of air to be rapidly purged from the mask interior (see applicants' specification at page 6, line 25 to page 9, line 29; see also Examples 4-13).

Although the resultant different structure and benefits of applicants' invention have not been taught in the prior art, they have, however, been utilized by investigators in this field after publication of applicants' invention. For example, the Louis M. Gerson Company introduced a mask in approximately March of 2001 (see attached McGinley Affidavit at paragraph 4.h.; copy attached as file Exhibit F — a sample of the Gerson mask is attached to this Appeal Brief as Exhibit G). The Gerson mask uses a flapper-style valve where a curved flap is positioned relative to the orifice to be pressed towards the seal surface under any orientation of the mask.

Before publication of applicants' invention, Gerson sold masks that used button-style valves. In addition, Magidson — an inventor of the subject matter used in the '972 Moldex patent mentioned above — described the use of a button-style valve on a filtering face mask in a 1988 patent application. But after the publication of applicants' invention, Magidson (in U.S. Patent 6,047,698 to Magidson et al. also assigned to Moldex-Metric Inc. and filed on August 20, 1998) described a flapper-style valve 14 that supports a flexible flap 20 on a valve seat 22 such that the flap 20 is curved over the orifice area and is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve:

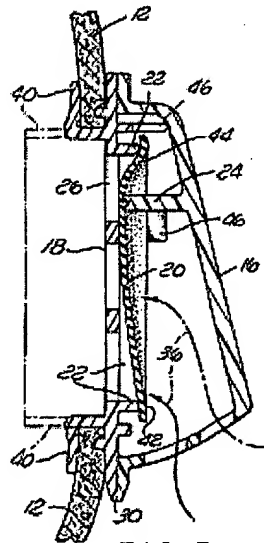


FIG. 3

[Magidson Valve - Moldex]

A sample of the Moldex valve is attached to this Brief as Exhibit H. For comparison purposes, a commercial sample of the inventive mask (3M 8511 Mask) is attached as Exhibit I. Thus, while

investigators in the pertinent field did not appreciate applicants' invention before it was published, these same investigators did choose to adopt it once it became publicly known.

ISSUES ON APPEAL

Issue 1 - Obviousness

Applicants' independent claim 33 has been rejected based on a combination of GB 2,072,516A to Simpson and U.S. Patent 3,191,618 to McKim. Simpson describes a flapper-style exhalation valve for a filtering face mask that operates under temperatures and pressures generated by a human's respiratory system and at a person's breathing pace (typically 20 to 60 cycles per minute), and McKim describes a curved seat reed valve for a 2-cycle engine that would operate at internal combustion temperatures and pressures and at speeds on the order of 10,000 or 12,000 revolutions per minute (rpms). Simpson's valve is made from plastic material, whereas McKim's reed valve is made of rigid spring sheet material such as shim stock. Would Simpson and McKim have rendered the subject matter of claim 33 obvious to a person of ordinary skill under the terms of 35 USC § 103(a)?

GROUPING OF CLAIMS

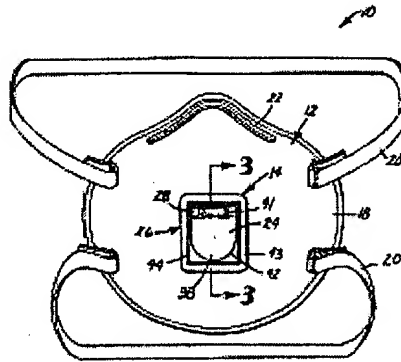
The appealed claims will stand or fall together. No admission, however, is being made with respect to the obviousness of the subject matter of the dependent claims with respect to the subject matter of the independent claims.

ARGUMENTS OF APPELLANTS

There are six reasons why applicants' invention would not have been obvious to a person of ordinary skill.

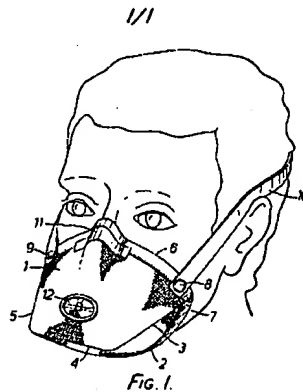
1. No Teaching or Suggestion of the Important Claimed Features in Either Simpson or McKim.

Neither Simpson nor McKim teaches or suggests placing a flapper-style exhalation valve on a filtering face mask directly in front of where the wearer's mouth would be when the mask is worn:



[Applicants' FIG. 1]

In Simpson, the exhalation valve is placed on the top portion 7 of its duck-billed mask so that the valve can take advantage of gravity to keep the flap pressed against the seal surface under neutral conditions, that is, when a wearer is neither inhaling nor exhaling:



[Simpson's Mask]

Simpson needs to place its valve in this particular location because the flap is not pressed towards the seal surface in an abutting relationship with it, under any orientation of the valve, when a fluid is not passing through the orifice. The Board's attention is directed in particular to Simpson's Figure 2, where it can be readily noticed that there is no prestress imposed upon the flap that would cause it to be pressed towards the seal surface when a fluid is not passing through the valve orifice:

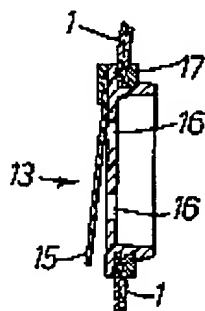
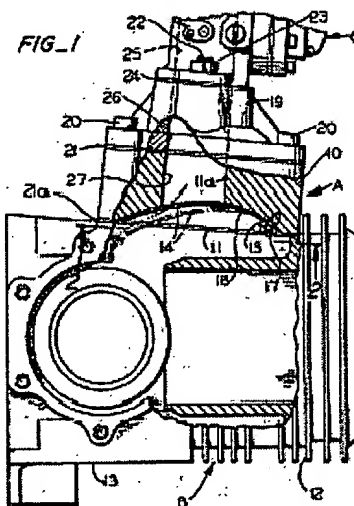


FIG. 2.

[Simpson Flapper Valve]

The Simpson flap 15 can only be pressed towards the seal surface under the force of gravity when the mask is oriented in an upright position. When a wearer tips their head downward, the mask cannot take advantage of gravity, and the flap may droop away from the seal surface. This movement can allow contaminants to enter the mask interior. With the valve on the top surface of a duck-billed mask, Simpson's valve can use gravity as opposed to a curved flap to keep the valve closed.

McKim discloses its valve 14 on the inside of an internal combustion engine:



[McKim Engine]

McKim does not address valve placement on a face mask because it describes a reed valve for a 2-cycle engine.

In addition, neither Simpson nor McKim suggests that the orifice in a flapper-style exhalation valve should have a cross-sectional area of greater than about 2 square centimeters. In regard to the size of the orifice, Simpson only shows two small openings 16 (see Simpson's Fig.

2 above). As indicated in applicants' specification, the orifice size should be greater than about 2 square centimeters and the valve should be mounted in the direct path of the exhale flow stream so that a greater percentage of exhaled air can be purged through the valve, and after an initial positive pressure to open the valve, the pressure inside the mask can greatly decrease and in some cases can become negative. See applicants' specification at page 5, lines 3-16. In some instances, it may be possible, in applicants' invention, for the percent total flow through the valve to be greater than 100% — that is, it may exceed the amount of air exhaled by the wearer. This means that applicants' inventive mask may beneficially act as an aspirator, which draws cool ambient air into the mask during an exhalation (see Examples 8-13 and Table 2 of applicants' specification). In addition to providing an aspiration effect, the filtering face mask of the present invention can also demonstrate a lower airflow resistance force, which enables the exhalation valve to open easier. These two attributes (aspiration and airflow resistance force) can be achieved by the positioning the exhalation valve directly in front of the wearer's mouth and by defining a preferred cross-sectional area ($> \sim 2 \text{ cm}^2$) for the orifice of the flapper-style exhalation valve.

Further, neither Simpson nor McKim addresses the ability to keep contaminants out of the mask interior by keeping the valve closed under any orientation of the mask. Simpson discloses the use of an antechamber for preventing valve leakage, and McKim does not deal with the issue at all because it does not disclose a filtering face mask or an exhalation valve.

Because Simpson and McKim both fail to appreciate the structure and benefits of applicants' invention, the combination of references would not have made applicants' invention obvious to a person of ordinary skill under the terms of 35 USC § 103.

2. McKim is Not Analogous.

Secondly, applicants' claims are patentable over Simpson and McKim because McKim cannot be applied as a secondary reference in making this rejection. McKim is not directed to an analogous art that would allow it to be cited under 35 USC § 103. As the Board is aware, a reference cannot be considered sufficiently analogous and thus relevant for determining obviousness unless it is either (1) within the field of the inventor's endeavor, or (2) is reasonably

pertinent to the particular problem that confronted the inventor.² Applicants' invention resides in the field of filtering face masks that use exhalation valves. McKim does not reside within this field of endeavor: it resides in the field of gasoline engines that use reed valves.

McKim shows a curved seat reed valve that is designed for use in a 2-cycle engine, which would turn at speeds as high as 10,000 or 12,000 revolutions per minute. In contrast, applicants' invention pertains to a filtering face mask that employs an exhalation valve, which opens in response to a wearer's breathing. Castiglione explained in his November 15, 1999 Affidavit (Exhibit C) why McKim does not reside in the field of endeavor of applicants' invention:

The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinary different design parameters.

Another investigator who works in the filtering face mask field, John L. Bowers, explains in more detail why McKim is not in the field of endeavor of a person of ordinary skill in the art designing exhalation valves:

My review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.

The field of the above-captioned '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow warm, moist, exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves generally operate at normal room temperatures and pressures.

The field of endeavor for filtering face mask is very different from the field of endeavor of a reed valve that is used in a two-cycle engine. Exhalation valves for respirators operate under very different conditions from valves that are used in

² *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

two-cycle engines and require notably different design parameters. The valve that is described in McKim has very rapid opening and closing requirements (thousands of openings and closings per minute) and operates under temperatures and pressures that differ substantially from the requirements of exhalation valves, which open and close under the much slower pace of a wearer's breathing and under temperatures and pressures that tend to vary only from the ambient to that exhibited by the wearer's exhaled air. Thus, persons of ordinary skill in the field of designing filtering face masks, to the best of my knowledge and experience, do not find valves for two-cycle engines to be in their field of endeavor and therefore do not consult documents that describe valves for these engines when developing new respiratory products.

Bowers' Affidavit, paragraphs 11-13 (Exhibit B). Another person skilled in the field of exhalation valves for filtering face masks, Frank Fabin, who has worked on one design team and led another design team in the development of a new exhalation valve, stated the following with respect to McKim:

My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The reed valve is disclosed to be made of a spring sheet material, such as, for example, shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.

In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.

Filtering face masks possess the problem of creating a warm, moist, high CO₂ content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy. Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO₂ content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient

environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

Fabin Affidavit, paragraphs 8-10 (December 10, 2001) (Exhibit D). In view of this evidence, it is clear that McKim does not reside in the field of endeavor of a person who designs exhalation valves for use on filtering face masks. Because the Examiner has not put forward any evidence to the contrary, the only conclusion that can be reached is that McKim is not in applicants' field of endeavor.

Since the first element of the two-part test for evaluating whether a reference is analogous has not been satisfied, it therefore is necessary to consider whether the McKim reference is reasonably pertinent to the particular problem that concerned applicants. The Federal Circuit has explained that *the USPTO needs to consider the purposes of the reference disclosure and the invention* in determining whether a reference meets the second prong of the two-part test:

A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it** (emphasis added).³

³ *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

In developing their invention, applicants purpose was to produce an exhalation valve that minimized exhalation pressure needed to open the valve and allowed a greater percentage of exhaled air to be purged through the exhalation valve to improve wearer comfort (see applicants' specification at page 3, line 25 to page 5, line 34 and Examples 4-6 and 8-13). The McKim reference, however, deals with solving the problem of float or bounce, which may occur when a 2-cycle engine is operating at high rpms (see McKim at column 1, lines 20-24 and column 2, lines 55-62). McKim's concern for controlling float or bounce is not reasonably pertinent to the problems that applicants were involved with — namely, providing comfort to the mask wearer by allowing the valve to open under minimal pressure and enabling a greater percentage of exhaled air to be purged through from the mask interior through the valve. As stated in the Bowers Declaration (Exhibit B), investigators who work in the field of exhalation valves for filtering face masks are not concerned with problems of float or bounce:

In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

The Castiglione and Fabin declarations (Exhibits A, C, and D) discussed above also explain how McKim is concerned with a problem that is of no concern to the purpose of the present invention.

In the leading case that deals with "analogousness" under part (2) of the test, the Federal Circuit explained that the USPTO needs to consider the purposes of the reference disclosure *and* the invention in determining whether a reference is reasonably pertinent to the particular problem that confronted the inventor.⁴ In *In re Clay*, the Federal Circuit found the cited reference to be not analogous when (1) the prior art taught the use of a gel within a natural, underground, oil-bearing formation to channel flow in a desired direction and (2) the applicant, Clay, had invented the use of a gel to fill the confined dead volume of a man-made storage tank. Although the inventor Clay and the prior art (Sydansk) both described technology that related to the use of gels in the petroleum industry, *the prior art Sydansk reference was found to be nonanalogous because the purpose of the Sydansk teachings were different from the purpose of the Clay invention.* Sydansk was faced with the problem of recovering oil from rock, which was not pertinent to the problem with which Clay was involved, namely, preventing loss of stored product in a tank's dead volume. The court also recognized that the subterranean formation of Sydansk was not structurally similar to and did not operate under the same temperature and pressure and did not function like Clay's storage tanks.⁵

As in *In re Clay*, the McKim reference also does not have the same purpose as applicants' invention, it does not operate under the same temperature and pressure, and it does not function like the claimed invention. Float or bounce is a problem that occurs when 2-cycle engines operated at high rpms (10,000 to 12,000 rpms). It has not been a problem that occurs in exhalation valves, which open and close in cadence with a person's breathing, about 20 to 60 cycles per minute. In addition, internal combustion engines operate at extraordinarily higher temperatures and pressures than a person's exhalation breath and are not powered by a person's lungs but by gasoline combustion. Finally, McKim's valve is used for intake into a combustion cylinder while the present valve is used for exhaust from the interior gas space of a mask.

⁴ *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it (emphasis added)"**)

⁵ *See, Clay*, 23 USPQ2d at 1601 ("Moreover, the subterranean formation of Sydansk is not structurally similar to, does not operate under the same temperature and pressure as, and does not function like Clay's storage tanks.").

A summary of the facts in *In re Clay* are provided below for ease of reference:

In re Clay	Result: reference <u>not</u> analogous					
	<i>Description</i>	<i>Problem to be Solved</i>	<i>Purpose</i>	<i>Operating Conditions</i>	<i>Similarities</i>	<i>Differences</i>
Clay	use of gel to displace liquid product from tank dead volume	preventing loss of stored product to tank dead volume	to displace liquid product from dead tank volume	<ul style="list-style-type: none">• subterranean rock• high temps (115°C) and bore pressures	both used in petroleum industry	different purposes and operating under different temperatures and pressures
Prior Art Sydansk	use of gel to fill anomalies in natural oil-bearing conditions	recovering oil from rock	to channel flow in a desired direction	<ul style="list-style-type: none">• made storage tank• ambient temp and pressure		
In re Japuntich et al.	Result: not yet decided					
Applicants' Invention	use of a new flapper-style exhalation valve in a filtering face mask	keeping valve closed under any orientation while allowing low pressure drop during an exhalation	to allow valve to open easier during an exhalation but remain closed under neutral conditions	<ul style="list-style-type: none">• exhale valve on face mask body• body temperatures• low pressures• cadence of person's breathing	both relate to valves	different purposes and operating under different temperatures, pressures, and speeds
Prior Art McKim	use of new reed intake valve in a two-stroke engine	stopping flutter or bounce of reed valve while operating under high RPM conditions	to eliminate float or bounce of valve reed to improve power and efficiency of engine	<ul style="list-style-type: none">• intake valve on 2-cycle engine• high temps• high pressure• high speeds (10-12,000 rpms)		

The Federal Circuit stated that when the reference "is directed to a different purpose [than the applicants' invention], the inventor would accordingly have less motivation or occasion to consider it" and therefore it would not be analogous.⁶ The purposes of both the invention and the prior art must be considered in ascertaining whether a reference resides in an analogous field. Because the Examiner only considered the purpose of McKim's valve in determining whether McKim is analogous, the Examiner has erred in making the assessment of whether the reference

⁶ *Id.*

is properly analogous. This error, in turn, has caused the Section 103 rejection to be improperly maintained.⁷

3. McKim Does Not Address Required Properties of Applicants' Valve and Thus There Can Be No Expectation that McKim's Teachings Could Suitably Be Used in Simpson.

Even if McKim was found to be an analogous reference, a person of ordinary skill still would not have been led to applicants' invention because the structure of the reed valve disclosed in McKim would not answer the required properties of applicants' valve. There is no evidence that the McKim reed valve would demonstrate the required flexibility of applicants' flexible flap.

Applicants have defined the term "flexible" to mean that "the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see, e.g., Fig. 5)."⁸ The flap that is described in McKim is made of "spring sheet material, such as, for example, shim stock" (column 1, lines 59-61). McKim therefore is not describing a flexible flap that would be suitable for use in an exhalation valve. This fact is confirmed by Richard Betts, a person skilled in the art of two-cycle engines:

Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the

⁷ See also, *SRI Int'l, Inc. v. Advanced Tech. Lab.*, 45 F.3d 443, 445 (Fed. Cir. 1995) ("The problem Green solved was how to compensate for changes in the spectral distribution of the return ultrasonic signal, with time or depth of penetration into a living organ, for enhanced image resolution and/or signal to noise ratio. The Minton reference, which relates to seismic prospecting circa 1946, almost thirty years prior to Green's filing date, would not have logically commended itself to Green's attention in considering how to compensate for changes in the spectral distribution of a received ultrasonic signal in an object such as a body part."); *In re Green*, 22 F.3d 1104, 1105 (Fed. Cir. 1994) ("A person of ordinary skill in the aircraft vane art simply would not find a 1919 reference about broken blades in a pugging mill reasonably pertinent to this problem."); *In re Butera*, 1 F.3d 1252, 1253, 28 USPQ2d 1399, 1400 (Fed. Cir. 1993) ("Butera's design is for air fresheners and insect repellents, while Hodge's is for metal ball anodes. The design of Hodge involves a different type of article from Butera's design and it is not analogous. One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode. Since Hodge is not analogous, the Board clearly erred in finding Hodge to be citable as prior art. Therefore there was no basis for rejecting Butera's claimed design as obvious."); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864, 26 USPQ2d 1767, 177_ (Fed. Cir. 1993) ("Wang's SIMMs were designed to provide compact computer memory with minimum size, low cost, easy repairability, and easy expandability. In contrast, the Allen-Bradley patent relates to a memory circuit for a larger, more costly industrial controller. SRAMs were used by Allen-Bradley because of their intended industrial environment. According to Dr. Frey, size was not a consideration in the Allen-Bradley work. Thus, there is substantial evidence in the record to support a finding that the Allen-Bradley prior art is not reasonably pertinent and is not analogous.").

⁸ Applicants' specification at page 7, lines 11-14.

mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

Declaration of Richard Betts, paragraph 5 (December 7, 2001) (Exhibit E). Because McKim's valve reed is so structurally different from the flexible flap that is used in the present invention, there would be no reason to expect — and there is no evidence in this record to indicate otherwise — that McKim's method of mounting its stiff valve reed would be suitable for a more highly flexible flap that is used on an exhalation valve in cantilevered fashion. Further, the conditions under which the McKim reed valve operates (high pressure, high temperatures, 10,000 or so cycles per minute) is so remarkably different from the conditions under which an exhalation valve operates (lung pressure, exhaled air temperatures, and breathing cycles of 20-60 per minute), that there can be no expectation that any structure described in McKim would be suitable to produce a operative valve that does not leak and that opens under minimal pressure like the one under consideration here. Valve opening and closure requirements for exhalation valves demand thorough design work and testing to ensure sound performance. Thus, the mounting requirements for the McKim cannot be transferred to an exhalation valve like Simpson's without a clear teaching or suggestion to do so.

4. No Teaching or Suggestion to Combine Simpson and McKim.

The rejection cannot be sustained because the record is devoid of any teaching, suggestion, or motivation to combine Simpson and McKim. As the Board is aware, an obviousness rejection cannot be sustained, based on a combination of references, without any evidence of why a person of ordinary skill would have been motivated to combine the pertinent teachings.⁹ The suggestion to make the combination must come from the prior art.¹⁰ It is not

⁹ *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) ("When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.").

¹⁰ *In re Beattie*, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) ("The question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.").

enough to simply identify each claimed element in the prior art.¹¹ "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."¹²

Simpson's teachings are mainly concerned with producing a face mask that is in the shape of a pouch and that has an exhalation valve. Simpson's valve teachings are not concerned with showing how to make a low pressure drop valve that can remain closed under a variety of orientations as they are concerned with simply illustrating alternative valves that could be used on its pouch-shaped mask. And McKim's teachings are for providing a curved reed valve seat on a 2-cycle gasoline engine to reduce float or bounce.

On page 5 of the January 28, 2003 Office Action, the Examiner states that the reason for combination of Simpson et al. with McKim is because "it would have provided for seating quickly, effectively, and without float or bounce after each opening as taught by McKim." Although not necessary to overcome the rejection, applicants have nonetheless responded to this unsupported position by furnishing testimony of an expert in the field of exhalation valves, John Bowers. Bowers states that "under the airflows and pressure drops that are encountered in the filtering face mask, 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, although the motivation cited by the Examiner apparently did not exist in the exhalation valve art, the Examiner nonetheless totally ignores the evidence of record. The Examiner's inability to cite any prior art source in support of his views for making the combination is clear legal error. The Federal Circuit has explained at length in *In re Lee* that obviousness rejections based on combinations of references are improper when there is no evidence in the record to support the reasoning behind making the combination. Conclusory statements simply are not evidence.¹³

¹¹ *Rouffet* at 1457. ("If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability.").

¹² *In re Lee*, 61 USPQ 1431, 1433 (Fed. Cir. 2002).

¹³ See *In re Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation" would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. The factual

Not only has the Patent Office erred by failing to supply the record with any evidence for making the combination, the Patent Office also has still further erred in totally disregarding the testimony of Bowers. The reviewing courts have stated on numerous occasions that it is not proper for Examiners to disregard — or substitute their viewpoint for — the evidence supplied by persons who are skilled in the technology at hand.¹⁴ The MPEP is in accord:

Evidence traversing rejections must be considered by the Examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action....Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient.¹⁵

If the Examiner chooses to continue down this path, applicants request that he furnish the record with evidence that shows why his views should be adopted over those of an expert. Until there is such evidence in the record, which evidence demonstrates that a person of ordinary skill would have combined the teachings of Simpson with McKim, the obviousness rejection based on these references cannot be properly held to constitute a *prima facie* case of obviousness.¹⁶

question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority."); see also *In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'.").

¹⁴ See, *In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 54 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967). Therefore, because the qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); see also *In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description.").

¹⁵ MANUAL OF PATENT EXAMINING Procedure § 2144.03, 2100-129 (August 2001).

¹⁶ See *Lee* at 1458. (The Federal Circuit reversed a Board decision because it "did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.").

5. References Provide Good Evidence for Not Combining.

Fifthly, the Simpson and McKim documents each present very good evidence of a lack of motivation to combine their respective teachings. The McKim technology was known to persons of ordinary skill before the Simpson publication. Nonetheless, Simpson did not employ the McKim technology in its flapper-style exhalation valve, even though Simpson and McKim both disclose flapper-style valves (albeit in entirely different fields). If the particular structure necessary for causing the flap to be pressed towards the seal surface would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's. The Board should notice that a very long time has passed since McKim's publication in 1962 and its disclosure of a curved flapper-style valve, but that particular technology did not find its way into use in the exhalation valve art at any point over this large time span. If this aspect of the present invention would have been obvious to a person of ordinary skill, the skilled artisan in the respirator art would have been expected to employ it sometime within those years. A prolonged existence of unused technology provides very good evidence of nonobviousness.¹⁷ Simpson, which was published almost 20 years after McKim and filed more than about 12 years before the effective filing date of the present application, also did not use this technology or find it to have been obvious. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the prior knowledge of the McKim technology and the long time that has elapsed since McKim's first publication, coupled with the failure to use this technology in a flapper valve system, presents very good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.¹⁸

¹⁷ See *Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, "would not have been obvious" under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic' referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

¹⁸ See *In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag *thoriated* tungsten filament or any way of producing it.").

6. Evidence of Copying Further Establishes Nonobviousness.

The copying of the technology of applicants' invention shortly after its publication further establishes its non-obviousness. As the Board is aware, the reviewing courts have relied on evidence of copying to find an invention to be not obvious to a person of ordinary skill.¹⁹ For example, in *Specialty Composites v. Cabot Corporation*,²⁰ the Federal Circuit stated that "[c]opying the claimed invention, rather than one in the public domain, is indicative of unobviousness."²¹ Secondary considerations like copying must always be considered in connection with an obviousness determination.²²

An examination of Exhibit H reveals a cantilevered flexible flap that is curved over the orifice and is pressed towards the seal surface in a substantial abutting relationship with it. This product is described in U.S. Patent 6,047,698 to Magidson et al., which was filed on August 20, 1998, after applicants' invention was publicly disclosed. But Moldex' earlier work reveals that button-style valves were used on Moldex' filtering face masks (see U.S. Patent 4,873,972 to Magidson et al.). And the more recent '698 Magidson patent (which describes the Exhibit H valve) states the benefits of using the technology claimed in this patent application:

Specifically flap 20 is shown in FIGS. 3 and 4 to be contoured to have a gentle curve inward completely around the circumference of the flat valve seat 22.

The off center contouring of the flexible flap 20 therefore provides for a sufficient holding force for the flap 20 to lie against and seal to the valve seat 22 and to have a free end 42 and a secured end 44.

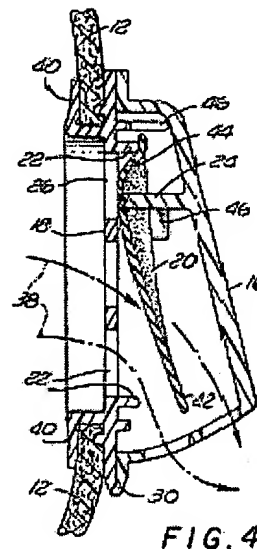
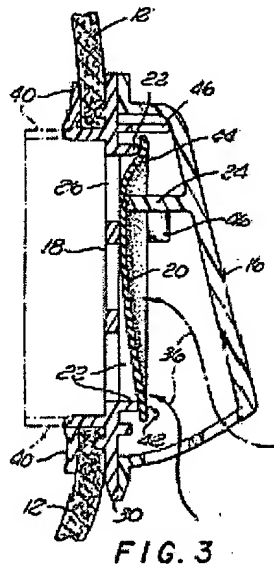
¹⁹ See e.g., *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1564, 7 USPQ2d 1548, 1554 (Fed. Cir. 1988) (Copying is additional evidence of nonobviousness."); *Diversitech Corp. v. Century Steps, Inc.* 850 F.2d 675, 679, 7 USPQ2d 1315, 1319 (Fed. Cir. 1988) ("Copying is an indicium of nonobviousness, and is to be given proper weight."); *Dow Chemical Co. v. American Cyanamid Co.*, 816 F. 2d 617, 622, 2 USPQ2d 1350, 1355 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 849 (1987) (the conclusion that the claimed invention would not have been obvious is supported by evidence of commercial success and acts of the infringer in trying but failing to "develop the claimed invention and [then copying] it instead"); *Windsurfing International, Inc. v. AMF Inc.*, 782 F.2d 995, 1000, 228 USPQ 562, 565 (Fed. Cir. 1986), ("copying the claimed invention, rather than one within the public domain, is indicative of non-obviousness").

²⁰ 6 USPQ2d 1601, Fed. Cir. 1988.

²¹ *Id.* at 1608.

²² *In re Sernaker*, 217 USPQ 1, 7 (Fed. Cir. 1983) ("If, however, a patent applicant properly presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness."); see also *W.L. Gore & Assoc. Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983) ("As discussed more fully below, the district court erred in specifically declining to consider the objective evidence of nonobviousness."); Manual of Patent Examining Procedure 2100-90 (Feb. 2000).

(Column 2, lines 32-40). Moldex illustrates the technology in Figs. 3 and 4:



Another product of similar structure, which also was introduced after the publication of applicants' invention has been sold by Survivair (See McGinley Affidavit - Exhibit F).

The use of the technology of applicants' invention by other respiratory product manufacturers after publication of applicants' invention provides very good evidence that the invention would not have been obvious to a person of ordinary skill. Although Simpson's teachings had been known for many years before applicants' filing date, there is no evidence that any competitor had previously introduced a product that is similar to the exhalation valve that is described and claimed in the present application. The introduction of such products after the publication of applicants' invention, however, further establishes that person's skilled in the filtering face mask art surely did not find obvious the subject matter of applicants' invention.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application under 35 USC § 103. Please reverse the decision below.

Respectfully submitted,

April 5, 2004

Date

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APPENDIX

33. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer, the mask body comprising a filtration layer through which inhaled air may pass before being inhaled by a wearer of the face mask; and

(b) an exhalation valve that is attached to the mask body directly in front of where the wearer's mouth would be when the mask is worn, the exhalation valve allowing air exhaled by a wearer to pass from an interior of the mask body to its exterior without having to pass through the filtration layer, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is circumscribed by the seal surface, the orifice having a cross-sectional area greater than about 2 square centimeters; and

(2) a single flexible flap that has only one stationary portion and only one free portion and a circumferential edge, the circumferential edge having a first segment that is associated with the only one stationary portion of the flap so as to remain at rest during an exhalation and having a second segment that is associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second segment of the circumferential edge also being located below the first segment when the filtering face mask is worn on a person, the flexible flap being mounted to the valve seat such that the one free portion of the flap exhibits a curvature over the orifice area when viewed from the side in the closed position and is pressed towards the seal surface in an abutting relationship with it, under any orientation of the exhalation valve, when a fluid is not passing through the orifice.

34. The filtering face mask of claim 33, wherein the flexible flap is not wholly circular in configuration when viewed from the front.

35. The filtering face mask of claim 33, wherein the second segment of the circumferential edge has a circular curvature that corresponds to a circularly shaped seal surface disposed beneath the second segment of the flap's circumferential edge.

36. The filtering face mask of claim 33, wherein the valve seat has a flap retaining surface, the flexible flap being mounted to the flap-retaining surface.

37. The filtering face mask of claim 36, wherein the flap retaining surface is planar.

50. The filtering face mask of claim 33, wherein the valve seat includes a flange portion that defines a mounting surface for the valve seat, which surface extends 360° around the valve seat at its base and enables the valve seat to be secured to the mask body.

51. The filtering face mask of claim 33, wherein the flexible flap assumes a curved profile, when in its closed state, that extends in from where the flexible flap contacts a retaining surface on the valve seat to where the second portion of the flexible flap contacts the seal surface of the valve body portion.

52. The filtering face mask of claim 33, wherein the flap retaining surface is oriented transversely relative to the orifice.

53. The filtering face mask of claim 52, wherein the flap retaining surface is positioned adjacent one side of the orifice.

55. The filtering face mask of claim 33, wherein the flexible flap is mounted to the valve seat in cantilever fashion.

56. The filtering face mask of claim 33, wherein the valve seat is made from a relatively light-weight plastic that is molded into an integral one-piece body.

57. The filtering face mask of claim 33, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface, and wherein the flexible flap would normally assume a flat configuration when no forces are applied to it.

58. The filtering face mask of claim 57, wherein the bias towards the seal surface is generated by the mounting of the flap to the valve seat.

59. The filtering face mask of claim 58, wherein the flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C.

60. The filtering face mask of claim 59, wherein the flexible flap is made from a crosslinked polyisoprene.

61. The filtering face mask of claim 58, wherein the flexible flap has a Shore A hardness of about 30 to 50 and has a generally uniform thickness of about 0.2 to 0.8 millimeters.

62. The filtering face mask of claim 33, wherein the flexible flap is longer in the direction extending from the first segment of the circumferential edge to the second segment.

63. The filtering face mask of claim 33, wherein the first segment of the flexible flap is about 10 to 25 percent of the total circumferential edge of the flexible flap, and the second segment is about 75 to 90 percent being free to be lifted from the seal surface.

64. The filtering face mask of claim 44, wherein the flexible flap and valve cover are positioned on the valve seat such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

65. The filtering face mask of claim 33, wherein the mask body is cup-shaped and comprises (1) a shaping layer for providing structure to the mask, and (2) a filtration layer.

66. The filtering face mask of claim 33, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

67. The filtering face mask of claim 33, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

68. The filtering face mask of claim 67, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth.

69. The filtering face mask of claim 36, wherein the flap-retaining surface is not disposed substantially in the path of the exhale flow stream.

70. The filtering face mask of claim 33, wherein the orifice includes a plurality of openings, which plurality of openings are disposed within the orifice beneath the point where the flexible flap is mounted to the valve seat when viewing the filtering face mask from the front in an upright position.

71. The filtering face mask of claim 70, wherein the exhaled air passes primarily through a plurality of openings during an exhalation.

72. The filtering face mask of claim 71, wherein the valve seat includes a flap-retaining surface that is located outside the region defined by the plurality of openings.

73. The filtering face mask of claim 37, further comprising a valve cover, the valve cover having an opening that allows exhaled air to pass therethrough and also having a surface that holds the flexible flap against the flap-retaining surface on the valve seat.

74. The filtering face mask of claim 73, wherein the flexible flap is mounted to the valve seat by mechanical clamping.

75. The filtering face mask of claim 74, wherein the flap-retaining surface is disposed on the valve seat on one side of the seal surface.

76. The filtering face mask of claim 37, wherein the flap-retaining surface includes two securement points both disposed outside a region encompassed by the orifice.

77. The filtering face mask of claim 36, wherein the curvature in the flexible flap extends from a point where the flap is mounted to the valve seat to a second point where the free portion of the flexible flap makes contact with the seal surface.

78. The filtering face mask of claim 77, wherein the curvature does not have an inflection point.

79. The filtering face mask of claim 33, further comprising a valve cover that has an opening that permits exhaled air to pass therethrough, the valve cover also having a fluid-impermeable ceiling that increases in height in the direction of the flexible flap from the first segment of the circumferential edge towards the second segment of the edge.

80. The filtering face mask of claim 76, wherein the opening in valve cover is positioned directly in the path of fluid flow approximately parallel to the path traced by the second segment of the circumferential edge during opening and closing of the free portion of the flexible flap.

81. The filtering face mask of claim 33, wherein the valve seat's orifice is circular and has cross-members disposed within the orifice.

82. The filtering face mask of claim 33, wherein the valve seat includes one or more cross members that are disposed within the orifice of the valve seat.

83. The filtering face mask of claim 81, wherein the cross members are slightly recessed beneath the seal surface when viewed from a side elevation.

84. The filtering face mask of claim 81, wherein the shape of the orifice, when viewed from the front, does not wholly correspond to the shape of the seal surface.

85. The filtering face mask of claim 33, wherein the valve seat includes a peripheral flange for mounting the exhalation valve to the mask body, the valve seat also having a seal ridge that extends upwardly so that the seal surface is upwardly spaced relative to the peripheral flange.

86. The filtering face mask of claim 33, wherein the orifice has a cross-sectional area that is greater than about 3 square centimeters.

87. The filtering face mask of claim 33, wherein the orifice has a cross-sectional area of less than 6 square centimeters.

88. The filtering face mask of claim 87, wherein the cross-sectional area is less than about 4 square centimeters.

LISTING OF EXHIBITS

- A. Affidavit of David M. Castiglione dated February 2, 2001
- B. Declaration of John L. Bowers dated December 10, 2001
- C. Affidavit of David M. Castiglione dated November 15, 1999
- D. Affidavit of Frank J. Fabin dated December 10, 2001
- E. Declaration of Robert Betts dated December 7, 2001
- F. Affidavit of Brian S. McGinley dated June 28, 2001
- G. Gerson Mask
- H. Moldex Mask
- I. 3M Mask

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Serial No.: 08/240,877

Filed: May 11, 1994

For: UNIDIRECTIONAL FLUID VALVE

Group Art Unit: 3761

Examiner: A. Lewis

AFFIDAVIT OF DAVID M. CASTIGLIONE

I, David M. Castiglione, swear as follows:

1. That I am presently a product development engineer at 3M Company in St. Paul, Minnesota.
2. That I received a Bachelor of Science degree in Materials Engineering from the Rensselaer Polytechnic Institute, which I received this degree in May of 1990. I also have a Masters of Science degree in Materials from the University of California at Santa Barbara. I received this degree in 1992.
3. That I began work at the 3M Company in St. Paul, Minnesota after receiving my Masters of Science degree from the University of California. I began work with 3M in the Automotive Engineered Systems Division and worked in that division through September of 1993.
4. That I began work for the Occupational Health & Environmental Safety Division (OH&ES) in October of 1993 and continue to work in that division at the present time. My work with the OH&ES division has entailed the design and development of respirators and respirator components. I have also worked with the study and maintenance of exhalation valves for negative pressure respirators. These duties have included evaluating the performance of exhalation valves as well as their function. I have calculated the percent flow through the valve,

EXHIBIT A

as well as analyzing the dynamic performance of the valve during simulated exhalation flows. I have also analyzed competitive designs of exhalation valves for negative pressure respirators.

5. That I have filed six United States patent applications for the OH&ES Division since I began employment with this business unit. The six patent applications include three utility patent applications and three design patent applications.

6. That I have reviewed U.S. Patent Application Serial No. 08/240,877 and the claims that are presently pending in this application. That I understand that the application claims a filtering face mask that comprises a mask body and an exhalation valve. I further understand that the exhalation valve includes a valve seat and a single flexible flap. The single flexible flap has a fixed portion and one free portion. The one free portion of the flexible flap is pressed towards the seal surface of the valve seat in an abutting relationship with it when the wearer is neither inhaling nor exhaling.

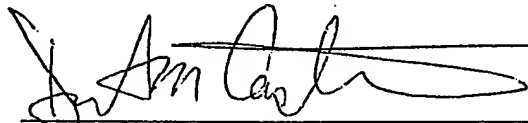
7. That I have reviewed UK Patent Application GB 2072516A. This patent discloses a respiratory face mask in the form of a pouch (1, 2) that is shaped to cover the nose and mouth of a wearer. The pouch is formed from a filtration effective sheet material and is provided with unidirectional exhalation valves (12, 13, 14). In Figure 2, a flap valve 13 is shown that comprises a flexible circular flap member 15 that is arranged to cover and close valve openings 16 during an inhalation. Flap member 15 flexes away from these openings 16 during an exhalation.

8. That I have reviewed the Office Action mailed November 8, 2000, and understand that the Examiner has taken the position that the free portion of the flexible flap disclosed in Figure 2 is "pressed toward the seal surface in an abutting relationship therewith when the wearer is neither inhaling or exhaling."

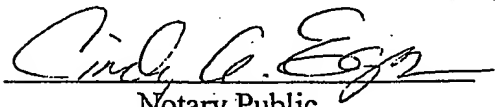
9. That I do not agree with the position taken by the Examiner at the bottom of page 3 of the Office Action. My review of the '516 UK patent application leads me to the conclusion that the valve 13 shown in Figure 2 does not have its flap 15 pressed towards the seal surface in an abutting relationship when the wearer is neither inhaling or exhaling. The '516 application reveals two distinctly different valves: a flap valve 13 as shown in Figure 2; and a diaphragm valve 14 as shown in Figure 3. These flaps have distinctly different constructions and operate differently. The valve shown in Figure 2 has a flat seal surface. The mounting of the flap 15 to

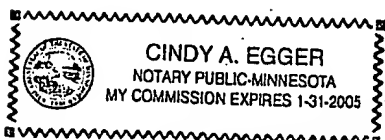
the seal surface at the top or fixed portion of the flap does not show a preload on the flap 15. There is nothing that can be discerned from Figure 2 or from the specification that would indicate that the flap is pressed towards the seal surface in its neutral position. And because Figure 3 shows a flap 18 resting upon the seal surface in the flap's neutral position while Figure 2 shows the flap 15 dangling away from the seal surface in an apparent neutral position also, it can be concluded that the valve 13 of Figure 2 would only become pressed against the seal surface during an inhalation. A review of the '516 UK application thus leads me to believe that the valve shown in Figure 2 is a unidirectional exhalation valve that prevents the influx of contaminants through the exhalation valve during an inhalation when it is most needed. It is not apparent to me that the valve would be pressed towards the seal surface under a neutral condition when the wearer is neither inhaling nor exhaling.

10. That I further understand that the Examiner has interpreted the '516 UK application to disclose a flexible flap that is pressed towards the seal surface because of the disclosure presented in Figure 3. This Figure, however, discloses a "button-type valve" where a flexible circular valve member 18 is centrally mounted by hub 21. This valve is different in structure and function from the valve shown in Figure 2, and therefore any teaching which shows that the flexible flap 18 engages a circular knife-edge valve seat 19 is not applicable to the flap valve presented in Figure 2.


David M. Castiglione

Subscribed and sworn to before me
this 2 day of February, 2001.


Notary Public



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Group Art Unit: 3761

Serial No.: 08/240,877

Filed: May 11, 1994

Examiner: A. Lewis

For: UNIDIRECTIONAL FLUID VALVE

DECLARATION OF JOHN L. BOWERS

I, John L. Bowers, state as follows:

2. I have been working in the respiratory field for about the past 15 years and am very familiar with the art pertaining to personal respiratory protection devices, including filtering face masks that are worn over the nose and mouth of a person and that use an exhalation valve to purge warm, moist, exhaled air from the mask interior.

3. I hold two U.S. patents in the respiratory field, including U.S. Patent 5,687,767 to Bowers, originally assigned to Racal Health & Safety Limited, England. This patent describes a unidirectional flapper-style fluid valve that is useful as an exhalation valve on a filtering face mask.

4. I am familiar with the subject matter of the above-captioned application.

5. I used to be an employee at Racal Health & Safety Limited prior to the acquisition of its assets by 3M. I worked at Racal for 9 years and had the title of operations and technical manager. In that position, I was responsible for health and safety product development, particularly for respiratory masks.

6. I presently hold the position of site manager in the Occupational Health & Environmental Safety Products Division (OH&ESD) at the 3M Company, 12-16 Bristol Road, Greenford Middlesex, England. In this position I am responsible for the day to day operation of the manufacturing and distribution centers for powered and supplied air respirators.

7. While working at Racal, I was assigned the responsibility to develop a new exhalation valve for its respiratory masks. Racal had a number of customer requests for a mask

that had an exhalation valve to purge warm, moist air from the mask interior. In considering candidates for exhalation valves on our respiratory products, I initially looked at conventional button-style valves. These valves, however, were not selected for widespread commercialization of Racal face masks because the cracking pressure required to open the button-style valve was found to be relatively high. I found that the central pivoting point created an undesirably higher opening force.

8. As part of the process for designing a new valve, I examined the exhalation valve that was recently commercialized by 3M. This valve is described in U.S. Patent 5,325,892 to Japuntich et al. I not only examined an actual commercial embodiment of the 3M valve, but I also carefully reviewed the disclosure of the '892 3M patent.

9. My evaluation of the 3M valve showed a product that had better performance than the conventional button-style valves. This evaluation led me in pursuit of developing a flapper-style valve similar to the 3M valve. The valve that was ultimately designed by me for Racal was the flapper-style unidirectional fluid valve that is shown in U.S. Patent 5,687,767 to Bowers, and a sample of which is attached to this Declaration as Exhibit G. I sought to design a valve that would avoid infringement of the issued 3M '892 patent and would be patentable over its disclosure. The filtering face mask that was developed, which employed the new Racal valve that I developed, did possess some features similar to the 3M valve and borrowed technology learned from the 3M valve. In particular, I designed the exhalation valve for Racal so that the flexible flap of the Racal valve was secured non-centrally relative to the orifice and had a free portion that was pressed against the seal surface when a wearer was neither inhaling nor exhaling, and the flap had a curvature in the free portion when viewed from the side elevation in a closed position (although the Racal valve that I designed was also made to have a transverse curvature). The flap was also designed to have stationary and free portions with a circumferential or peripheral edge that had stationary and free segments, respectively. The flap was secured to the valve seat at the flap-retaining surface closer to the stationary segment of the peripheral edge than to the free segment. Other than the transverse curvature, the features described in the three previous sentences were present in the 3M valve and were discovered from my examination of the 3M product and the published '892 patent. The Racal valve thus was able

to remain closed under neutral conditions under any orientation, like the 3M valve, to prevent the influx of contaminants and was also able to open under a relatively small exhalation force.

10. I have also read U.K. Patent Application GB 2072516 to Simpson et al. (Simpson) and U.S. Patent 3,191,618 to McKim, and I do not believe that the combination of Simpson and McKim would have led a person of ordinary skill in the art to the present invention. In my view, the McKim patent is not pertinent to the subject matter sought to be patented in the above-captioned U.S. Patent Application Serial No. 08/240,877 and is not pertinent to the subject matter taught in Simpson.

11. My review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.

12. The field of the above-captioned '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow warm, moist, exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves generally operate at normal room temperatures and pressures.

13. The field of endeavor for filtering face mask is very different from the field of endeavor of a reed valve that is used in a two-cycle engine. Exhalation valves for respirators operate under very different conditions from valves that are used in two-cycle engines and require notably different design parameters. The valve that is described in McKim has very rapid opening and closing requirements (thousands of openings and closings per minute) and operates under temperatures and pressures that differ substantially from the requirements of exhalation valves, which open and close under the much slower pace of a wearer's breathing and under temperatures and pressures that tend to vary only from the ambient to that exhibited by the wearer's exhaled air. Thus, persons of ordinary skill in the field of designing filtering face

masks, to the best of my knowledge and experience, do not find valves for two-cycle engines to be in their field of endeavor and therefore do not consult documents that describe valves for these engines when developing new respiratory products.

14. In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

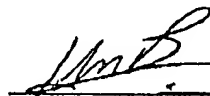
15. My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior

when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

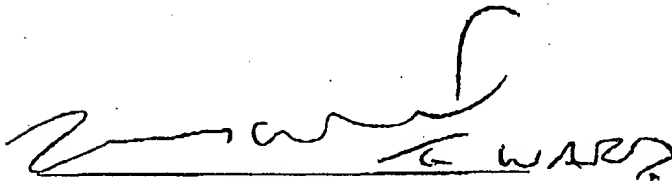
16. The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

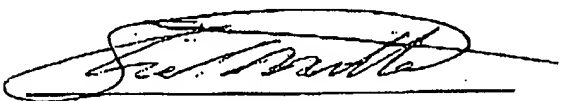
Dated this Ten day of December, 2001.



John L. Bowers



Witness



Witness
STUART MILLER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Serial No.: 08/240,877

Filed: May 11, 1994

For: FILTERING FACE MASK THAT HAS A NEW
EXHALATION VALVE

Group Art Unit: 3761

Examiner: A. Lewis

AFFIDAVIT OF DAVID M. CASTIGLIONE

I, David M. Castiglione, swear as follows:

1. That I am presently a product development engineer at 3M Company in St. Paul, Minnesota.
2. That I received a Bachelor of Science degree in Materials Engineering from the Rensselaer Polytechnic Institute. I received this degree in May of 1990. I also have a Masters of Science degree in Materials from the University of California at Santa Barbara. I received this degree in 1992.
3. That I began work at the 3M Company in St. Paul, Minnesota after receiving my Masters of Science degree from the University of California. I began work with 3M in the Automotive Engineered Systems Division and worked in that division through September of 1993.
4. That I began work for the Occupational Health & Environmental Safety Division (OH&ES) in October of 1993 and continue to work in that division at the present time. My work with the OH&ES division has entailed the design and development of respirators and respirator components. That I have filed five United States patent applications for the OH&ES Division since I began employment with this business unit. The five patent applications include three utility patent applications and two design patent applications.

EXHIBIT C

5. That I am familiar with U.S. Patent Application Serial No. 08/240,877 filed May 11, 1994. I have read the specification and claims in this patent application and also have read the Decision of the Board of Patent Appeals and Interferences' Decision on Appeal mailed September 14, 1999.

6. That I understand that the Board has held that subject matter of independent claims 18 and 24 to be unpatentable based on the disclosures in U.S. patents 2,320,770 to Cover and 3,191,618 to McKim. I further understand that the Board has concluded "that it would have been further obvious to one of ordinary skill in the art at the time the invention was made to have modified Cover's valve 46 to be attached to the modified valve seat outside a region encompassed by a single opening/orifice as suggested by the teachings of McKim to permit the valve seat to quickly, effectively, and without bounce after each opening thereof (sic)."

7. That I have read U.S. Patents 2,320,770 and 3,191,618, and I do not believe that the combination of Cover and McKim would have led a person of ordinary skill in the art to the present invention because the McKim patent is not pertinent to the subject matter sought to be patented in U.S. Patent Application Serial No. 08/240,877. Nor do I believe that the McKim disclosure is pertinent to the subject matter described in Cover. I do not believe that the McKim patent satisfies the legal criteria for being art analogous to the invention claimed in U.S. Patent Application Serial No. 08/240,877.

8. That my review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which would turn at speeds as high as 10,000 or 12,000 revolutions per minute. The reed valve described in McKim is particularly suited for a high speed operation where opening and closing forces are large. These forces can cause the valve to bounce (an elastic recoil from impact). The stated goals in McKim are full rapid opening, quick and complete closing, and eliminating float and bounce. The curved seat reed valve described in McKim is an intake valve for a two-stroke engine. The valve operates when the piston in the engine's cylinder moves from a top dead center to a bottom dead center, and the pressure within the crankcase is reduced below atmospheric pressure to overcome the spring bias of the valve reed. The valve then opens and remains open until the difference in these pressures is reduced sufficiently to allow the spring bias of the reed to return to its seat.

9. That the subject matter of the '877 invention, as I understand it, pertains to a filtering face mask that has a mask body adapted to fit over the nose and mouth of a person and also includes an exhalation valve that is attached to the mask body. The exhalation valve comprises a valve seat that has an orifice through which a fluid can pass and that has a seal ridge that circumscribes the orifice and has a concave curvature when viewed from a side elevation. The flexible flap has a first portion that is attached to the valve seat outside a region encompassed by the orifice. A second portion of the flexible flap assumes a concave curvature of the seal ridge when the valve is in a closed position and is free to be lifted from the seal ridge when a fluid is passing through the orifice.

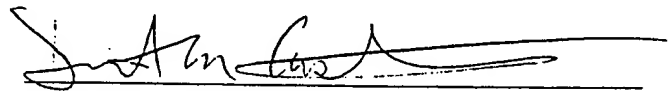
10. That the field of the '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow more moist exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves operate at normal room temperatures and low pressures. The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinarily different design parameters.

11. That in exhalation valves for filtering face masks, the speed of opening is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, at the airflows and pressure drops that are encountered in a respiratory mask, "bounce" is not an occurring event. Investigators in the exhalation valve art for filtering face masks seek to produce exhaust valves that minimize force to open from the normally closed position. This particular design parameter is not compatible with fast-closing valves that require high forces for rapidly opening and closing. The flow volumes and flap stiffnesses are orders of magnitude higher for valves used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art

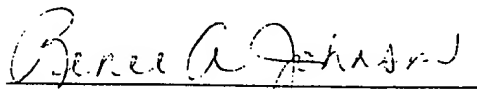
would not have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask.

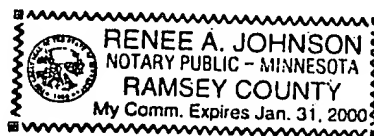
12. That the curved seat reed valve described in the McKim patent does not have the same purposes as the exhalation valve that is used in the present invention and that the McKim reed valve does not relate to the same problem that has been encountered in designing the filtering face mask of U.S. Patent Application 08/240,877. The reed valve described in the McKim patent is too remote to be pertinent to the subject matter sought to be patented in U.S. Patent Application 08/240,877.

13. That U.S. Patent 2,320,770 to Cover describes a respirator, which is designed to be worn by a person for purposes of preventing the wearer from inhaling airborne contaminants. The reed valve described in McKim would not be applied to the Cover respirator for the reasons recited above, particularly because a person of ordinary skill in the respirator art would not consult a document pertaining to a valve for a high speed gasoline engine when looking to modify a respirator or an exhalation valve for a respirator.


David M. Castiglione

Subscribed and sworn to before me
this 15th day of November, 1999.


Notary Public



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Group Art Unit: 3761

Serial No.: 08/240,877

Filed: May 11, 1994

Examiner: A. Lewis

For: UNIDIRECTIONAL FLUID VALVE

AFFIDAVIT OF FRANK J. FABIN

I, Frank J. Fabin, being duly sworn, state as follows:

1. I presently hold the position Technical Manager for the Respirator Systems Business Unit of the Occupational Health and Environmental Safety Products Division (OHESD) at the 3M Company, St. Paul, Minnesota.

2. I received a Bachelors of Science degree in mechanical engineering from the University of Maryland in 1970. I also have received a Masters of Business Administration from the University of St. Thomas, St. Paul, Minnesota, in 1979.

3. I began work for the OHESD in 1977 as an engineer in division engineering. From 1981 to 1991, I worked in product automation and new product development for OHESD. During the period of 1990 and 1991, I was the action team leader for the development of an exhalation valve that resulted in an invention that is the subject matter of the above-captioned patent application. Before being the action team leader for this valve development assignment, I was also on the product development team for the respirator valve that was the subject of U.S. Patent 4,934,362 to Braun. From about 1992 to present, I have been the Technical Manager for the Respirator Systems Business Unit of the OHESD. In this capacity, I have overseen the development of positive pressure respirators and elastomeric face pieces and the components that are used on these products, including exhalation valves.

4. I have obtained about 4 issued U.S. patents for the OHESD since I began employment with this business unit.

5. I am familiar with the subject matter of U.S. patent application Serial No. 08/240,877.

EXHIBIT D

6. I understand that the Examiner has held the subject matter of claim 78 to be unpatentable based on the disclosures in U.K. patent application GB 2072516A to Simpson et al. (Simpson) and U.S. Patent 3,191,618 to McKim. I understand that the Examiner has concluded that "[i]t would have been obvious to modify the flexible flap and seat of Simpson et al. (fig. 2) to be curved because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (col. 1, lines 64-72)."

7. I have reviewed the Simpson and McKim patent disclosures, and I do not believe that a person of ordinary skill in the filtering face mask art would have combined the teachings of these references. I do not believe that a person of ordinary skill would be motivated to look at references in the valve art for gasoline engines for solutions to problems confronted in the filtering face mask field or the exhalation valve art field. I further do not believe that the subject matter of the McKim patent is pertinent to the subject matter described in Simpson. Nor do I believe that the McKim disclosure is pertinent to the subject matter sought to be patented in the above-captioned U.S. patent application Serial No. 08/240,877.

8. My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The reed valve is disclosed to be made of a spring sheet material, such as, for example, shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.

9. In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.

10. Filtering face masks possess the problem of creating a warm, moist, high CO₂ content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy. Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO₂ content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

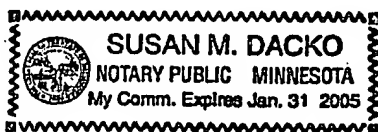
11. The present invention was concerned with providing a filtering face mask that would not allow contaminants to enter the interior of the mask through the valve and would, at the same time, be comfortable to the wearer by displacing as large a percentage of exhaled air as possible through the exhalation valve with minimal effort. The present invention is concerned with "(1) minimizing exhalation pressure inside a filtering face mask, (2) purging a greater percentage of exhaled air through the exhalation valve (as opposed to having the exhaled air pass through the filter media), and under some circumstances (3) providing a negative pressure inside a filtering face mask during exhalation to create a net flow of cool, ambient air into the face mask." The art of reed valves for gasoline engines is not a source, to my knowledge, that has ever been consulted by persons who develop filtering face masks and the exhalation valves that are used on them. Nor

to my knowledge has the art for reed valves for gasoline engines ever been consulted to deal with the nature of the problems that were attempted to be solved by those who develop exhalation valves for filtering face masks. I am not aware of one instance where persons of ordinary skill in the filtering face mask or exhalation valve art has found reed valves for gasoline engines to be reasonably pertinent to problems that they encounter in the development of these products. In all of my years of working in this field, and in supervising others who work in this field, I have not seen one instance where a reference to a reed valve for a gasoline engine has been one that would have logically commended itself to the attention of an investigator in the field of developing filtering face masks or exhalation valves or would have been consulted to overcome problems that are confronted in the design of such products.


Frank J. Fabir

Subscribed and sworn to before me
this 10th day of December, 2001.


Notary Public



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Group Art Unit: 3761

Serial No.: 08/240,877

Filed: May 11, 1994

Examiner: A. Lewis

For: UNIDIRECTIONAL FLUID VALVE

DECLARATION OF ROBERT BETTS

I, Robert Betts, state as follows:

1. In 1965 I began building and repairing 2 and 4-cycle engines and continue to do so today.

2. I presently work for and own Assault Motor Sports, a unit of General Tool and Engineering Inc. Assault Motor Sports is involved in producing and modifying high-performance 2-stroke engines. In the past year alone, I estimate that I have constructed over 30 2-cycle, high-performance engines, all of which have had reed valves. The total number of 2-cycle engines that I have either built or worked on in my 36+ years probably exceeds 250 engines.

3. I have reviewed U.S. Patent 3,191,618 to C.D. McKim. This patent describes a curve seat reed valve that is useful in a 2-cycle engine. In particular, the patent discloses a valve reed 14, of spring sheet material, such as, for example, shim stock, that is secured by an anchor bar 15 and screw 17 to a curve seat 18 that is formed on the inner or engine side of a valve block 10. The main thrust of the disclosure in the McKim patent is to the use of the curved valve seat 18, which is configured to conform to the normal curvature of the valve reed 14. To define this curvature, the valve reed 14 is mounted at an end portion 27 as shown in Fig. 3 and is stressed by applying a T-shaped member 30 at the free end 29 of the reed 14. The flexed curvature that is created is reproduced on the valve seat 18.

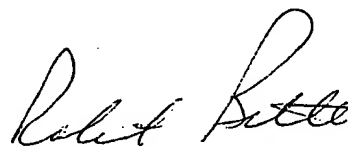
4. I have also reviewed the disclosure in U.S. Patent application Serial No. 08/240,877. I understand that this application discloses an exhalation valve for a filtering face mask. The exhalation valve uses a flexible flap as the dynamic member for opening and closing the valve. The application defines the term flexible to mean that "the flap can deform or bend in the form of a

self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see e.g., Fig. 5)."

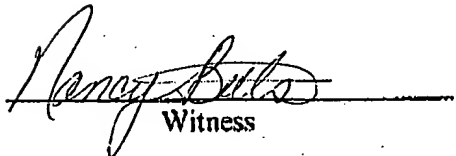
5. Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated this 7th day of December, 2001.



Robert Betts



Witness



Witness

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Serial No.: 08/240,877

Filed: May 11, 1994

For: UNIDIRECTIONAL FLUID VALVE

Group Art Unit: 3761

Examiner: A. Lewis

AFFIDAVIT OF BRIAN S. MCGINLEY

I, Brian S. McGinley, being duly sworn, state as follows:

1. I presently hold the position of Product Marketing Manager in the Occupational Health & Environmental Safety Products Division (OH&ESD) at the 3M Company, St. Paul, Minnesota. In this position I am responsible for pricing, promotion, packaging, and positioning of 3M OH&ESD respiratory products.

2. I have been working in the respiratory field for the past 18 years and am very familiar with the art pertaining to personal respiratory protection devices, including filtering face masks that are worn over the nose and mouth of a person and that use exhalation valves to purge warm, moist exhaled air from the mask interior.

3. I am familiar with the subject matter of the above-captioned patent application, and I have reviewed the claims pending in this application and understand their scope and content.

4. I have witnessed the evolution of the art in respiratory products, in particular the evolution of the exhalation valve art on filtering face masks. On information and belief, I believe that the following sequence of events has occurred in this field:

a. Before May 29, 1992, 3M invented a filtering face mask that comprised a mask body and an exhalation valve. The mask body was adapted to fit over the nose and mouth of a person and had a filtering layer for filtering air that passed through the mask body.

EXHIBIT F

The exhalation valve was attached to the mask body, and it comprised a valve seat that included an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also had a single flexible flap that had a stationary portion, one free portion, and a circumferential edge that included stationary and free segments. The stationary segment of the circumferential edge was associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation, and the free segment of the circumferential edge was associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge was disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

This filtering face mask differed from known commercial products in that the flexible flap was noncentrally secured to the valve seat (relative to the orifice) at the flap retaining surface, and the flap retaining surface and seal surface were nonaligned and positioned relative to each other to allow for a cross-sectional curvature of the one free portion of the flexible flap when viewed from the side in a closed position. The nonalignment and relative positioning of the flap-retaining surface and the seal surface also allowed for the free portion of the flexible flap to be pressed towards the seal surface when a fluid was not passing through the orifice and to allow for the free portion of the flexible flap to be lifted from the seal surface during an exhalation.

b. On December 9, 1993, the filtering face mask described in paragraph 4.a was first published in International Publication WO 93/24181. This new filtering face mask was also published in U.S. Patent 5,325,892 on July 5, 1994.

c. In 1993, OH&ESD introduced in Europe its filtering face mask product that had a valve that included the structure described above in paragraph 4a. An Example of this kind of valve is attached to this Affidavit as Exhibit A. This product meets all of the limitations of the broadest claim pending in the above-captioned application (claim 78).

d. Before 3M's publication and introduction of the new filtering face mask product referred to in paragraphs 4.a and 4.b, it is my understanding and recollection, that essentially all previous commercial filtering face mask products had used an exhalation valve that had a centrally-mounted flap. Known valves that had centrally-mounted flaps

mainly had a circular flap member that was mounted to a valve-seat through a central stake or button. These valves are commonly referred to in the art as "button-style" valves and had been used on 3M commercial filtering face masks for approximately 13 years before 3M's original filing date of the flapper-style valve of claim 78. Examples of button-style valves are shown in U.K. Patent Application 2,072,516A (Fig. 3) published 1981, U.S. Patent 2,895,472 (Fig. 5) published 1956, U.S. Patent 2,230,770 (Figs. 11-14, 27-29) published 1940, and U.S. Patent 4,630,604 (Figs. 1, 2 and 4-5) published 1986. Another centrally mounted valve — although not nearly as common — had been (and continues to be) sold by OH&ESD in Europe and is described in U.S. Patent 4,934,362 to Braun. This latter product is not referred to as a button-style valve. But the flap is centrally-mounted to the valve seat by a central bridge.

e. In 1995, Racal Health & Safety introduced in the United States a filtering mask that had a flapper-style valve. This new Racal mask had an exhalation valve that was similar to the structure and function of the flapper valve product that was previously published and introduced by OH&ESD and claimed in the above-caption application. A sample of this product is attached to this Affidavit as Exhibit B. This valve is also shown and described in Racal's U.S. Patent No. 5,687,767. Like the invention claimed in the present application, the Racal product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

f. Around approximately late 1998, Moldex Metric Inc. introduced in the United States a filtering face mask that also had a flapper-style valve. This new Moldex mask had an exhalation valve that was similar to the structure and function of the flapper valve

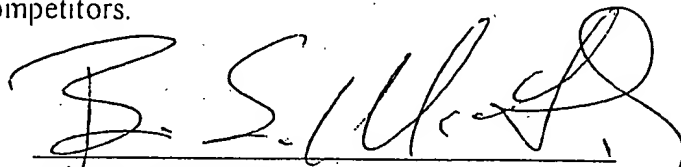
product that was previously published and introduced by OH&ESD and claimed in the above-captioned application. Moldex Metric sells this valve under the trademark Ventex™. A sample of this product is attached to this Affidavit as Exhibit C. This valve is also described in Moldex's U.S. Patent No. 6,047,698, filed August 20, 1998. Like the invention claimed in the present application, the Moldex product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

g. In approximately 1999, Ever Green Co. Ltd. of Korea introduced a filtration face mask product in that country, which mask was similar in structure and function to the respiratory product previously published and introduced by OH&ESD and claimed in the above-captioned application. A sample of their product is attached to this Affidavit as Exhibit D. Like the invention claimed in the present application, the Korean product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

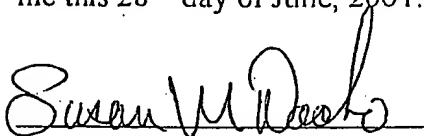
h. In approximately March of 2000, Louis M. Gerson Company introduced in the United States a filtering face mask product that was similar in structure and function to the filtering face mask previously published and introduced by OH&ESD and claimed in the above-captioned application in paragraphs 4. a-c above). An example of this product is attached to this Affidavit as Exhibit E. Like the invention claimed in the present application, the Gerson product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

i. In approximately November of 2000, Survivair (division of Bacou USA Safety Inc.) introduced a filtering face mask product that had an exhalation valve similar in structure and function to the exhalation valve previously published and introduced by OH&ESD and claimed in the above-captioned application. A sample of this product is attached to this Affidavit as Exhibit F. Like the invention claimed in the present application, the Survivair product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

5. The public disclosure and introduction of the OH&ESD filtration face mask product of the above-captioned invention — followed closely by five competitive products that share the same new technology previously disclosed and claimed in the above-captioned application, and coupled with the fact that no previous filtering face mask product used this technology but primarily relied on centrally-mounted flap valve technology, particularly button-style valves — lead me to the firm conclusion that the technology first created by OH&ESD and claimed in the present application was copied by each of these competitors.


Brian S. McGinley

Subscribed and sworn to before
me this 28th day of June, 2001.


Notary Public

